**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| LAWRENCE J. KONCELIK, JR., Individually and on Behalf of All Others Similarly Situated, Plaintiffs, | : | MEMORANDUM DECISION AND ORDER 08 Civ. 10262 (GBD) |
| -against- | : | |
| SAVIENT PHARMACEUTICALS, INC., CHRISTOPHER G. CLEMENT, and ZEBULUN D. HOROWITZ, Defendants. | : | |



GEORGE B. DANIELS, District Judge:

Lead Plaintiff Lawrence J. Koncelik, Jr. ("Plaintiff"), individually and on behalf of all other persons similarly situated, brought this action against Defendant Savient Pharmaceuticals, Inc and two of its officers, Christopher G. Clement and Zebulun D. Horowitz, (collectively "Savient"). Plaintiff alleges violations of Section 10(b) of the Securities and Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a) (the "Exchange Act"), and Rule 10b-5, 17 C.F.R. § 240.10b-5, and "control person" liability pursuant to Section 20(a) of the Exchange Act. Savient moves to dismiss Plaintiff's claims pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Savient's motion is granted.

## FACTUAL ALLEGATIONS

Plaintiff purports to represent a class of all individuals and entities that purchased Savient securities or options between December 13, 2007, and October 24, 2008, (the "Class Period"), and were thereby damaged. Plaintiff's allegations relate to Savient's representation of preliminary results of Phase 3 clinical trials of a drug called pegloticase, a product manufactured by Savient. The following facts taken from the complaint are assumed to be true and are construed in the light

most favorable to Plaintiff. See Blue Tree Hotels Investment v. Starwood Hotels & Resorts Worldwide, Inc., 369 F.3d 212, 217 (2d Cir. 2004).

Pegloticase is a drug targeted for the "treatment-failure gout population" characterized as having "very severe gout" that has failed to be effectively treated. Winke Decl. Ex. 1, at 1. The treatment-failure gout population is defined as having a "very high degree of co-morbidit[ies] such as hypertension [and] cardiovascular disease" making this population "exceptionally difficult to treat." The patients participating in the clinical trials are considered to be representative of the treatment-failure gout population and thus share the same issues. The Phase 3 clinical trials lasted from March 2007 to October 2007 and consisted of two patient groups – one group was given the drug product and the other a placebo. Thereafter, the data was "unblinded and analyzed" and subsequent press releases and conference calls about the preliminary results followed. Mot. to Dismiss, at 2. Plaintiff claims that misleading statements were made during the Class Period through a number of press releases and conference calls updating investors on the Phase 3 preliminary results of the clinical trials.

Savient's December 13, 2007 press release regarding the analyses of the Phase 3 clinical data stated that there was "no signal for adverse safety findings . . . except for the occurrence of infusion-related adverse events."[1] Winke Decl. Ex. 1, at 2. Infusion-related adverse events suggest that the chosen procedure in administrating the drug to patients during the clinical trials caused the event rather than the drug itself. In addition to the infusion-related adverse events, Savient notified the investing public of three deaths that occurred during the clinical trial by the following statement:

[1] At the end of Phase 3, patients were subsequently given the option to continue the treatment in an open-label extension study for up to 24 months. That data is not part of the present dispute. Mot. to Dismiss, at 2.

> Three deaths occurred in the treatment phase . . . including death in one patient who voluntarily withdrew consent for renal dialysis. A fourth patient, not included in the . . . population, died after completing the study when she elected to withdraw from antibiotic treatment of MRSA sepsis.

Id. (parentheses omitted). However, Savient quickly noted that "[n]one of the patient deaths *appear to* be casually related to pegloticase treatment, as judged by the clinical investigators and Savient medical monitors." Id. (emphasis added). The preceding statements from this press release are the only statements directly referring to the patient deaths and Savient's analysis of those deaths with regard to the clinical trials. Savient exemplified the clinical results of the drug in sum by stating that "[it] believe[d] that the preliminary top line results indicate[d] a *favorable risk-benefit ratio* justifying the use of pegloticase . . . in the treatment-failure gout population." Id. (emphasis added).

On February 4, 2008, Savient again stated that "[t]he assessment of safety across the two Phase 3 studies was reported to be favorable and to have shown that the only adverse safety signal was the occurrence of infusion reactions." Winke Decl. Ex. 2, at 1. The February 28, 2008 press release provided additional details on the data exclusively with regards to infusion-related events and the three deaths. On August 7, 2008, Savient held an analyst conference call for investors where Savient's Chief Executive Officer and President claimed the analyses from the Phase 3 clinical trials "continue to provide robust evidence of ongoing efficacy and safety in the treatment failure gout population over the treatment period." Winke Decl. Ex. 5, at 3. Savient's CEO further stated in the conference call:

> Ultimately on the market *I do not expect* any limitation to the duration of treatment. It will be a medical decision, a therapeutic decision, made by the physician, together with his -- with the patient . . . I *think* our dataset will be adequate to support chronic dosing without a limitation.

Id. at 13 (emphasis added).

Before September 26, 2008, Savient publicly stated that they were considering "broader strategic transactions." Winke Decl. Ex. 7, at 8. According to the CEO, this involved soliciting interest from potential business partners who had the "expertise and capabilities to commercialize" the drug. Id. "During the . . . process, [Savient] made available to . . . interested parties, all clinical, technical and commercial information about pegloticase." Id. However, on September 26, Savient announced that they "continue to evaluate strategic business development options," but "[t]here can be no assurance as to when or whether any transaction will be consummated." Am. Compl. ¶ 37. This statement was understood by some investors as indicating Savient's failure to secure a business partner. The CEO later revealed that Savient had seriously considered one offer from a major global pharmaceutical company to "acquire Savient outright" but that offer was later withdrawn as a "result of the serious and rapid worsening of the world financial markets [occurring] in late September and early October." Winke Decl. Ex. 7, at 8. Savient never secured a partner for the proposed business relationship.

On October 27, 2008, Savient issued a press release discussing in detail the cardiovascular Serious Adverse Events ("SAEs") experienced by patients taking pegloticase during the Phase 3 clinical trials. In that release, Savient provided the total number of cardiovascular SAEs, five *non-fatal* and three *fatal* cardiovascular SAEs, and that all those patients were exclusively in the drug group and not the placebo group. The reference to the three *fatal* cardiovascular SAEs represented the three deaths discussed in earlier disclosures. These three deaths were characterized in this press release explicitly as *fatal* cardiovascular SAEs. The five *non-fatal* cardiovascular SAEs were for the first-time disclosed to the investing public in this press release.

According to Plaintiff, the data disclosed in the October 27, 2008 press release – the total number of cardiovascular SAEs and the number of those that fell within the drug group versus the placebo group – altered the determination of the statistical significance between the drug pegloticase and the cardiovascular SAEs. Plaintiff contends that the cardiovascular SAEs were causally related to the drug given the new information disclosed, contrary to what was believed before the release. The press release cautioned that "[n]one of these cardiovascular events, including the patient deaths were thought to be casually related to pegloticase treatment by the Investigators or Sponsor." Winke Decl. Ex. 4, at 4. In their October 29, 2008 conference call with investors, Savient stated that the five cardiovascular SAEs did not warrant prior disclosure because of the extensive history of cardiovascular disease among the patient population.

In response to the perception taken by the investing public that the existence of cardiovascular SAEs, particularly if statistically significant, would greatly diminish the probability of FDA drug approval and restrict the marketability of the drug; Savient stock immediately plummeted over 70%. After the October 27, 2008 disclosure, Savient changed pegloticase's trade name from Puricase to Krystexxa and modified its proposed indication which initially was "for the control of uric acid in patients with gout whose signs and symptoms are inadequately controlled by conventional urate lowering therapy due to ineffectiveness, dose limiting toxicity, hypersensitivity or other contraindications." Am. Compl. ¶ 50-51. The proposed indication was changed after the October 27 press release to:

> [T]reatment-failure gout, or TFG, to control hyperuricemia and to manage the signs and symptoms of gout. TFG is gout in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with conventional urate-lowering therapy *at the maximum medically appropriate dose* or for whom conventional urate-lowering therapy is contraindicated.

Id. at 13-14 (emphasis added). This further confirmed investors' belief that the expected market reach of the drug had diminished. Investors suffered losses during the Class Period on Savient securities or options due to the disclosure of the five *non-fatal* cardiovascular SAEs.

In October 2008, Savient submitted its Biologics License Application ("BLA") to the FDA for permission to market and commercialize pegloticase. On June 16, 2009, the Arthritis Advisory Committee ("AAC") appointed by the FDA recommended the approval of pegloticase, Savient's drug product. In the AAC's briefing document used by the committee to determine whether to make a recommendation for the product's approval, the following statements pertaining to the cardiovascular SAEs were made:

> All of these events occurred in patients who had pre-existing comorbid risk factors for the development of major cardiac events. The occurrence of these events is not unexpected given the high prevalence of underlying cardiovascular disease in the patient population who participated in these trials . . . . However, there remains a degree of uncertainty about the cardiac safety of pegloticase because so few events were observed due to the limited number of subjects enrolled and limited duration of follow-up.

Winke Decl. Ex. 10, at 41.

Plaintiff claims that the investing class suffered losses due to speculative investments made on Savient securities or options during the Class Period based on the understanding that there were at most three cardiovascular SAEs, which represent the three deaths. Am. Compl. ¶ 72. Plaintiff alleges that the losses resulted after the October 27, 2008 press release revealed that there were actually eight cardiovascular SAEs including five *non-fatal* cardiovascular SAEs that were not previously disclosed with the three *fatal* cardiovascular SAEs. Plaintiff alleges that the new information revealed the statistical significance of the SAEs, which diminished the likelihood of drug approval and restricted the marketability of the drug. This caused the stock to plummet, according to Plaintiff. Plaintiff alleges that the losses that were suffered due to the new revelations

in the October 27, 2008 press release are actionable pursuant to Rule 10b-5 of the Exchange Act because the partial disclosure of the number of cardiovascular SAEs resulted in false and misleading representations.

Plaintiff alleges that Savient's disclosures in the press releases and conference calls regarding the drug pegloticase constituted material misrepresentations and omissions that were made with scienter, and are thus actionable pursuant to Section 10(b) and Rule 10b-5. Plaintiff bases the claim on Savient's failure to disclose the five *non-fatal* cardiovascular SAEs with the three *fatal* cardiovascular SAEs previously disclosed in the December 13, 2007 press release. Plaintiff further alleges that Savient failed to disclose that all of the cardiovascular SAEs had occurred to patients treated with pegloticase as opposed to those treated with a placebo. Plaintiff's complaint argues that Savient knowingly or recklessly misled investors by issuing a partial disclosure of the cardiovascular SAEs. Further, Plaintiff claims that Savient knew, or should have known, that reasonable investors would perceive the disclosure as complete and adequate and use the information to assess the drug's market potential. Plaintiff further alleges that Savient made false and misleading statements by promoting the data as "robust" and as showing a "favorable risk-benefit ratio" when Savient was in fact in possession of evidence that contradicted such statements.

**STANDARD OF REVIEW**

Dismissal pursuant to Fed. R. Civ. P. Rule 12(b)(6) is inappropriate "unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." See Blue Tree Hotels Investment, 369 F.3d 212, 217 (2d Cir. 2004) (citing Sweet v. Sheahan, 235 F.3d 80, 83 (2d Cir. 2000)). "In considering a [12(b)(6)] motion to dismiss a 10(b) action [of the Securities Act], we must accept all factual allegations in the complaint as true and must consider the

complaint in its entirety." Slayton v. Am. Express Co., 604 F.3d 758, 765 (2d Cir. 2010) (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007)). In reviewing the allegations, this Court may consider documents incorporated by reference into a complaint to assess the viability of the plaintiff's claims. See Tellabs, 551 U.S. at 322. Although it is generally inappropriate to assess the validity of the allegations on a motion to dismiss, the plaintiff cannot premise their claims on allegations flatly contradicted by such incorporated documents. See Gant v. Wallingford Bd. of Educ., 69 F.3d 669, 674 (2d Cir. 1995). In order to withstand a motion to dismiss, the plaintiff must set forth in the complaint "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. V. Twombly, 550 U.S. 544, 936 (2007); see also Ashcroft v. Iqbal, 129 S. Ct. 1937, (2009).

**RULE 10B-5**

Section 10(b) of the Securities Exchange Act of 1934 protects investors from corporations which use "manipulative or deceptive devices[s] or contrivance" in violation of the securities laws. See Tellabs, 551 U.S. at 318. For Plaintiff's Rule 10b-5 claim to withstand Savient's motion, the amended complaint must contain particularized facts demonstrating that "in connection with the purchase or sale of securities, the defendant, acting with scienter, made a false material representation or omitted to disclose material information and that plaintiff's reliance on defendant[s'] conduct caused plaintiff injury." See Caiola v. Citibank, N.A., N.Y., 295 F.3d 312, 321 (2d Cir. 2002) (internal citation and alterations omitted). Specifically, the Amended Complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Defendant argues that Plaintiff has not alleged

facts that support an inference that any misstatements or omissions were made with the required *scienter*.

**A. Scienter**

*Scienter* is found when the allegations demonstrate a strong inference of intent "to deceive, manipulate, or defraud, or reckless disregard for the resultant deception" stemming from a false or misleading statement. See, e.g., 15 U.S.C. § 78(u)-4(b)(2); AUSA Life Ins. Co. v. Ernst and Young, 206 F.3d 202, 207 (2d Cir. 2000). In order to demonstrate an inference of scienter, Plaintiff must either allege "facts to show that [D]efendants had both (a) motive and opportunity to commit fraud," or allege facts that "constitute strong circumstantial evidence of (b) conscious misbehavior or recklessness." See Chill v. G.E. Co., 101 F.3d 263, 267 (2d Cir. 1996) (internal quotations and citation omitted). Furthermore, Plaintiff must state with particularity facts demonstrating that a "reasonable person would deem the inference of scienter cogent and at least compelling as any opposing inference" of "nonfraudulent intent." Tellabs, 551 U.S. at 314, 324.

**1. Motive and Opportunity**

Plaintiff's allegations fail to establish that Savient had both motive and opportunity to commit securities fraud.[2] With respect to motive and opportunity, Plaintiff must allege that Defendants not only possessed a "distinct and concrete incentive" to commit fraud but also "the means and likely prospect of achieving [those] benefits by the means alleged." See Chill, 101 F.3d at 267-268 (allegations that defendants' motive was simply "to maintain the appearance of corporate profitability, or of the success of an investment" are insufficiently particularized to establish

[2] "Courts often assume that high ranking officers and directors of a corporation . . . have the opportunity to manipulate the stock of a corporation." In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 468 (S.D.N.Y. 2008).

scienter); see also In re Geopharma, 399 F. Supp. 2d 432, 450 (S.D.N.Y. 2005). A "generalized motive" is not "sufficiently concrete for purposes of inferring scienter." Chill, 101 F.3d at 268.

Plaintiff alleges that Savient intended to not disclose the five additional cardiovascular SAEs in order to avoid a "devastating impact on public and other potential partners' perception of the drug's approvability." Mot. in. Opp'n to Mot. to Dismiss, at 18. Plaintiff alleges that Savient's motive derives from its attempt to seek strategic business alternatives during the Class Period, including joint ventures with other companies. Plaintiff argues this is due to Savient's inability to manufacture and market pegloticase on a wide scale because of limitations on its dosage potential. Thus, according to Plaintiff, Savient was avoiding a "detrimental effect on its ability to explore strategic options" by initially concealing the five non-fatal cardiovascular SAEs from investors before the October 27 press release. Id.

Savient's alleged motive to secure a business partner before public disclosure of the five non-fatal cardiovascular SAEs may, on its face, appear to be a sufficient allegation for Plaintiff to survive a motion to dismiss. See Rothman v. Gregor, 220 F.3d 81 (2d Cir. 2000) ("[A]n allegation of a high stock price artificially maintained in the context of one impending acquisition" can strongly infer scienter, given the circumstances of this particular case.); In re Northern Telecom Ltd. Sec. Litig., 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders."). However, Plaintiff's allegations are not sufficiently particularized because the prospective partners that Savient sought to establish a business relationship with were in possession of all the data from the clinical trials, including all information regarding both *fatal* and *non-fatal* cardiovascular SAEs. Plaintiff does not identify any particular

fact that would show that prior public disclosure of the five non-fatal cardiovascular SAEs would have been material to a prospective partner's determination of whether to establish a business relationship with Savient. The fact that Savient still failed to obtain a partner without the public disclosure further weakens Plaintiff's theory. Therefore, Savient's alleged motive to maintain the perception of the drug's approvability simply rises to a generalized motivation, and is "not sufficiently concrete for purposes of inferring scienter." Chill, 101 F.3d at 268 (A generalized motive to justify investment and have it appear profitable, "one which could be imputed to any publicly-owned, for-profit endeavor, is not sufficiently concrete for purposes of inferring scienter.") (footnote omitted); see, e.g., Kalnit v. Eichler, 264 F.3d 131 (2d Cir. 2001) ("[T]he desire to achieve the most lucrative acquisition proposal can be attributed to virtually every company seeking to be acquired. Such generalized desires do not establish scienter."); San Leandro Emergency Medical Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 814 (2d Cir. 1996) (A company's desire to maintain high bond or credit rating, and thereby maximize marketability of and minimize interest rate on debt securities, does not qualify as sufficient motive for fraud.). Thus, the alleged motive to withhold prior disclosure of the five non-fatal cardiovascular SAEs until Savient secured a business partner does not sufficiently give rise to a concrete benefit that can sustain a Rule 10b-5 claim.

**2. Conscious Misbehavior or Recklessness**

Plaintiff's allegation also fails to establish circumstantial evidence of Savient's conscious misbehavior or recklessness. Plaintiff alleges that Savient was consciously misbehaving or reckless, in publicly disclosing the first three cardiovascular SAEs without disclosing the remaining five cardiovascular SAEs, because they knew or should have known that this established a statistically

significant link between the drug and the cardiovascular SAEs. Plaintiff contends that the statistical significance is clearly indicated by the number of cardiovascular SAEs in the drug group and the absence of any cardiovascular SAEs in the placebo group. Further, Plaintiff alleges that Savient knew or should have known that investors were going to interpret the initial disclosure of the number of cardiovascular SAEs as complete, and that the market would have responded differently to the information disclosed if given the above omitted data during the Class Period. Plaintiff additionally alleges that Savient failed to disclose that the patients that had a cardiac SAE exclusively belonged to the drug group. Thus, Plaintiff contends that the totality of the allegations demonstrates Savient's conscious misbehavior or recklessness.

With respect to recklessness or conscious misbehavior, Savient's conduct must have been "highly unreasonable and . . . represents an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Rolf v. Blyth, Eastman Dillon & Co., Inc., 570 F.2d 38, 47 (2d Cir. 1978) (citation omitted) (alteration in original). Similarly, "an egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness." Chill, 101 F.3d at 269 (quoting Goldman v. McMahan, Brafman, Morgan & Co., 706 F. Supp. 2d 256, 259 (S.D.N.Y. 1989)) (alteration in original).

Plaintiff's complaint fails to state particularized facts demonstrating how Savient was consciously misbehaving or reckless in disclosing the preliminary results pertaining to patient deaths without disclosing the non-fatal cardiovascular SAEs. See In re Tronox, Inc., No. 09-cv-6220(SAS), 2010 WL 2835545, at *10 (S.D.N.Y. June 28, 2010) ("[D]efendants played a role in a specific set of transactions that would have made them aware of, or given them access to,

information contradicting their public statements."). The word "cardiovascular" was not noted anywhere in any of the press releases prior to the October 27, 2008 press release. Plaintiff's argument that partial disclosure of the total number of cardiovascular SAEs deceived the investing public in believing they had complete information is unsubstantiated by the fact that there was absolutely no prior mention of cardiovascular SAEs to constitute a partial disclosure of such information. The press releases and conference calls strictly discussed the occurrence of deaths in the study and infusion-related SAEs, and that such occurrences did not appear to relate to the drug. Those discussions did not include any reference to the cardiovascular SAEs, fatal or non-fatal. In the October 27, 2008 press release, Savient only then characterized the deaths as cardiovascular SAEs, in addition to disclosing for the first time the five non-fatal cardiovascular SAEs. Plaintiff has failed to show how a reasonable investor could have understood any statement pertaining to the patient deaths as referring to cardiovascular SAEs prior to October 27, 2008, without the statement specifically characterizing the deaths as "cardiovascular."

Plaintiff has failed to provide any particularized facts, demonstrating an egregious refusal to see the obvious from the data gathered during the clinical trials, that would suggest a statistically significant relationship[3] between the drug pegloticase and the cardiovascular SAEs and thus require

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[3] A 'safety signal' is generally reported information on a possible causal relationship between an adverse event and a drug. When a safety signal is identified, further investigation generally follows to determine whether an actual connection exists. *Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)*, U.S. Food and Drug Administration, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm (last visited Aug. 5, 2010); see also *What is a Safety Signal?*, Pfizer, http://media.pfizer.com/files/health/medicine_safety/2-4_What_is_a_Safety_Signal.pdf (last visited Aug. 5 2010). An actual connection does not have to exist before disclosure is required. When it is found that there exists a statistically significant relationship, disclosure of that possible casual connection must be made to the investing public. Carter-Wallace I, 150 F.3d at 153, 157.

further disclosure.[4] In re Carter-Wallace, Inc., Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998) (Carter-Wallace I). Particularly, Plaintiff fails to provide particularized facts that any indication of a statistical significance should have been so obvious to Savient, even given the patients' extensive cardiac medical history. The clinical results revealing the number of patients that did experience a cardiovascular SAE and the fact that all those patients were exclusively in the drug group does not necessarily signal a statistical relationship. See In re Carter-Wallace, Inc., Sec. Litig., 220 F.3d 36, 40-41 (Carter-Wallace II) (rejecting the argument that the number of incidents was . . . statistically unacceptable and thus demonstrates conscious misbehavior or recklessness). In this case, "[all eight SAEs] occurred in patients who had pre-existing comorbid risk factors for the development of major cardiac adverse events."[5] Winke Decl. Ex. 10, at 41. Furthermore, the FDA described "[t]he occurrence of these events [as] not unexpected given the high prevalence of underlying cardiovascular disease in the patient population who participated in these trials."[6] Id. The FDA also noted that the "distribution of cardiovascular deaths and cardiac SAEs was not obviously unusual in view of the fact that they occurred in patients predisposed to such events and taking into account the unequal randomization in the clinical trials." Winke Decl. Ex. 10, at 52. Based on this

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[4] Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000) (listing cases where Plaintiffs sufficiently showed Defendants refusing to acknowledge the obvious.); Carter-Wallace I, 150 F.3d at 153, 157 (holding that the statements "did not become materially misleading until Carter-Wallace had information that Felbatol had caused a statistically significant number of aplastic-anemia deaths and therefore had reason to believe that the commercial viability of Felbatol was threatened").

[5] "The proportion of patients with medical history of cardiac disease in each of the groups was approximately 75 percent in the every two-week group, 77 percent in the every four-week group and 77 percent in the placebo group." Winke Decl. Ex. 10, at 41.

[6] "Rule 201 of the Federal Rules of Evidence provides that courts may only take notice of facts 'either (1) generally known…or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'" In re Pfizer, Inc. Sec. Litig., 584 F.

understanding of the patient population and considering collectively all the facts presented, it was not reckless for Savient not to provide such information to the investing public until determining the significance, if any, of the drug on the occurrence of SAEs. See Tellabs, 551 U.S. at 325; Carter-Wallace I, 150 F.3d at157. Savient therefore did not have the duty to disclose such information because of the uncertainty of the significance of the cardiovascular SAEs in the clinical trials. See Carter-Wallace I, 150 F.3d at157. Because Plaintiff's allegation fails to demonstrate that Savient egregiously refused to see the obvious, Savient could not be held to have known, or should have known, that there arguably existed a statistical significance that required disclosure. See id.

Plaintiff has failed to provide particularized facts that Savient acted with the belief that there was a casual relationship between the drug pegloticase and the cardiovascular SAEs, which could demonstrate an inference of *scienter*. See In re Pfizer, Inc. Sec. Litig., 584 F. Supp. 2d at 634-36 (defendants were in possession of some studies suggesting a statistical significant relationship between the drug and the adverse events which the court found to suggest scienter). On the contrary, Savient noted in their October 29, 2008 conference call why and how the five cardiovascular SAEs were not previously viewed as related to the drug and not warranted for prior disclosure.[7] Plaintiff has not raised any allegation that is at least as compelling as Savient's

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Supp. 2d 621, 634 (S.D.N.Y 2008) (quoting Fed. R. Evd. 201 (b)).

[7] The October 29, 2008 conference call contained the following statement:

> The five cardiac-related SAEs that were not previously reported or discussed were not reported by us because they were never viewed as pegloticase related adverse events by our investigators, our consultants or the company. The detailed medical histories of the patients, outlining their preexisting cardiovascular conditions and other comorbidities, their completion of the Phase 3 program and continuation in the open-label extension on drug without experiencing additional cardiac events led us to this conclusion.

statement that they believed the data lacked statistical significance to conclude a likely casual relationship between the drug pegloticase and the cardiovascular SAEs. Tellabs, 551 U.S. at 314, 324 ("[T]he inference of scienter must be more than merely "reasonable" or "permissible"--it must be cogent and compelling, thus strong in light of other explanations.").

Because Plaintiff has failed to show a strong inference of scienter that is at least as compelling as the opposing inference, he has failed to adequately plead a claim on this basis.

**B. False and Misleading Statements**

Even if it is found that Savient had the requisite state of mind, *scienter*, in making the statements regarding the data from the clinical trials, Plaintiff fails to show that Savient made false and misleading statements to the detriment of the investing public. Plaintiff alleges that Savient made misleading statements about the prospective market reach of the drug pegloticase since they were in possession of data that arguably contradicts such statements. The alleged false and misleading statements include: (1) "[W]e *believe* that the preliminary top line results indicate a *favorable* risk-benefit ratio," (2) "I *do not expect* any limitation to the duration of treatment," and (3) "*robust* evidence of ongoing efficacy and safety in the treatment failure gout population." (emphasis added).

"[A] defendant is not liable if the forward-looking statement is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." Slayton v. Am. Express Co., 604 F.3d 758, 765-66 (2d Cir. 2010); see, e.g., Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353,

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Winke Decl. Ex. 6, at 3-4. Further details supporting Savient's conclusion that the five cardiac-related SAEs were not causally related to the drug pegloticase are included in the October 29, 2008 conference call transcript. Winke Decl. Ex. 6, at 3-4.

371-72 (5th Cir. 2004); 15 U.S.C. § 78u-5(c). Neither is corporate optimism actionable under a claim of securities fraud. See, e.g., Slayton v. Am. Express Co., 604 F.3d 758 (2d Cir. 2010); Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004) ([E]xpressions of puffery and corporate optimism do not give rise to securities violations.").

The alleged false and misleading representations are based on the omission of the five non-fatal cardiovascular SAEs that, according to Plaintiff, would have illustrated a casual relationship between the drug and the cardiovascular SAEs if they were disclosed with the three fatal cardiovascular SAEs. Plaintiff, however, failed to show that Savient knew or should have known that there was a casual relationship, or that such a casual relationship actually existed to warrant prior disclosure of the five non-fatal cardiovascular SAEs. Therefore, Plaintiff's allegations fail to demonstrate "actual knowledge" to withstand the dismissal of his claim.

**C. Material Omissions**[8]

Plaintiff fails to show that material misrepresentations resulted in disclosure statements because of Savient's omitted data regarding the five non-fatal cardiovascular adverse events, even if it is found that Savient had the requisite state of mind, *scienter*. Plaintiff alleges that the omitted data would have altered a reasonable investor's investment decision on the prospective market reach of the drug pegloticase during the Class Period, thus making the omitted data material. Plaintiff attempts to demonstrate the materiality of the omitted data by pointing to the fact that the stock plummeted 70% once Savient disclosed the omitted data.

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[8] Savient limited its motion to disputing whether Plaintiff raised particularized facts that could support a finding of scienter and, given a possible finding of scienter by this Court, whether statements made by Savient were false and misleading. This Court will still determine whether the omissions or misstatements alleged to support a finding of scienter are material misrepresentations, a finding needed to support a 10b-5 claim.

To support a claim under Section 10(b), the materiality of an omitted fact depends on whether the disclosure of the fact is necessary to prevent a statement from being materially misleading. See Glazer v. Formica Corp., 964 F.2d 149, 156 (2d Cir. 1991); Kronfeld v. Trans World Airlines, Inc., 832 F.2d 726, 735 (2d Cir. 1987). To satisfy the materiality requirement, the omitted fact need not show "that a reasonable investor would necessarily change his investment decision based on the information." SEC v. Mayhew, 121 F.3d 44, 52 (2d Cir. 1997). Instead, demonstrating that "a reasonable investor would have viewed it as significantly altering the 'total mix' of information available" fulfills the materiality requirement. Id. However, drug companies do not have a duty to disclose "isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by – rather than randomly associated with – use of the drugs and are sufficiently serious and frequent to affect future earnings." Carter-Wallace I, 150 F.3d at 157. A "drug manufacturer's assurances about safety does not become materially misleading" until a statistically significant number of adverse events implies the drug's causation, and "therefore had reason to believe that the commercial viability" of the drug was threatened." Id. However, "materiality is a flexible, fact-based determination." In re Bayer AG Sec. Litig., No. 03-cv-1546(WHP), 2004 WL 2190357, at *9 (S.D.N.Y. September 30, 2004); see also Glazer, 964 F.2d 149, 156 (2d Cir. 1992) (rejecting "a bright-line test for materiality" since it is a fact-specific inquiry).

As discussed earlier, the statistical significance of the drug with regards to the cardiovascular adverse events was inconclusive based on the clinical trials on pegloticase. "Isolated adverse event reports, lacking statistical significance, do not prove that a drug is unsafe" and are thus not material. In re Bayer AG Sec. Litig., 2004 WL 2190357, at *9; see also Carter-Wallace I, 150 F.3d at 157.

Also, the fact that the stock plummeted 70% once Savient disclosed the five non-fatal cardiovascular events alone does not imply the materiality of the omitted data. Possible knowledge of lack of statistical significance "coupled with other evidence, can put a pharmaceutical company on notice concerning a drug's safety risks." In re Bayer AG Sec. Litig., 2004 WL 2190357, at *9. However, the stock price plummetting does not add evidence to the potential drug's causal relationship with the adverse events, and is not the kind of evidence that may support the materiality of the omitted data in spite of a lack of statistical significance. Given the inconclusive evidence of the adverse events, even if it could have significantly altered an investor's decision regarding Savient's securities and options, Savient was under no obligation to disclose such information. See Carter-Wallace II, 220 F.3d at 42 ("The early medical reports may have indicated a potential problem, but until a connection between Felbatol and any illness could be made, we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation."); see also Oran v. Stafford, 226 F.3d 275, 284 (3d Cir. 2000) (disclosure of adverse medical reports would not have altered "total mix" given FDA's conclusion that the relationship between drug and reported illnesses was inconclusive). Because Savient need not disclose data that is unreliable and unsubstantiated to the investing public, omitting the five non-fatal cardiovascular adverse events did not constitute a material misrepresentation.

**CLAIMS UNDER § 20(A) OF THE EXCHANGE ACT**

Plaintiff also moves pursuant to section 20(A) of the Exchange Act to hold Defendants jointly and severally liable. Section 20(A) provides that "controlling persons" may be held jointly and severally liable for a corporation's violations of the securities laws. See Boguslavsky v. Kaplan, 159 F.3d 715, 721 (2d Cir. 1998). To state a viable claim under this provision, Plaintiff must first establish a primary

violation of the securities laws. See Ganino, 228 F.3d at 170; see also In re Pfizer, Inc. Sec. Litig., 538 F. Supp. 2d 621, 637 (S.D.N.Y 2008) (Section 20(a) claim must be dismissed against individual defendants if plaintiffs have failed to state a *prima facie* violation under Section 10(b)). Plaintiff's claim under section 20(A) against the individual defendants, Clement and Horowitz, fails because Plaintiff failed to state a *prima facie* claim against Savient under section 10(b). Therefore, Plaintiff's claims against the individual defendants under section 20(A) must also be dismissed.

**CONCLUSION**

Savient's motion to dismiss is granted. Plaintiff is granted leave to move to file a second amended complaint.

Dated: New York, New York
September 27, 2010

SO ORDERED:

George B. Daniels

GEORGE B. DANIELS
United States District Judge